

Docket No.: HO-P02378US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Helene Derand et al.

Confirmation No.: 5350

Application No.: 10/069,827

Art Unit: 1753

Filed: December 11, 2000

Examiner: Barton, Jeffrey Thomas

For: MICROFLUIDIC SURFACES

SECOND AMENDED APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This amended appeal brief is filed in response to the Notice of Non-Compliant Appeal Brief dated April 23, 2007. Applicants believe that no fees are required for this submission.

The fees required under § 41.20(b)(2) have been previously paid.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

I.	REAL PARTY IN INTEREST.....	5
II.	RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS	5
III.	STATUS OF CLAIMS	5
	A. Total Number of Claims in Application	5
	B. Current Status of Claims.....	5
	C. Claims On Appeal.....	6
IV.	STATUS OF AMENDMENTS	6
V.	SUMMARY OF CLAIMED SUBJECT MATTER	6
VI.	GROUND OF OBJECTION TO BE REVIEWED ON APPEAL.....	7
	A. Whether claims 2-5, 7, 8, 10-13, 18-23, 28, 34, 35, 42, 43, 45, and 54 were properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202).....	7
	B. Whether claims 14 and 24-26 were properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claims 7 and 20 and in further view of Bergstrom et al. (US Pat No. 5,250,613).....	7
	C. Whether claims 15-17 were properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 11 and in further view of Malmsten et al., Effect of Chain Density on Inhibition of Protein Adsorption by Poly(ethylene glycol) Based Coatings, <i>Journal Of Colloid And Interface Science</i> 1998, vol. 202; no. 2, pages 507-517.....	7
	D. Whether claim 30 was properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202).	8

E.	Whether claim 45 was properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 35 and in further view of Daecher et al. (US Patent No. 5,840,388).....	8
F.	Whether claims 7 and 27 were properly rejected under 35 U.S.C. § 103(a) as unpatentable over Karger et al. (US Patent No. 5,840,388) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Van Alstine et al. (US Patent No. 4,690,749) and Regnier et al. (US Patent No. 5,958,202).....	8
VII.	ARGUMENT.....	8
A.	Rejection under 35 U.S.C. § 103(a) over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202).....	8
B.	Rejection under 35 U.S.C. § 103(a) over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claims 7 and 20 and in further view of Bergstrom et al. (US Pat No. 5,250,613).....	21
C.	Rejection under 35 U.S.C. § 103(a) over over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 11 and in further view of Malmsten et al., Effect of Chain Density on Inhibition of Protein Adsorption by Poly(ethylene glycol) Based Coatings, <i>Journal Of Colloid And Interface Science</i> 1998, vol. 202; no. 2, pages 507-517.	23
D.	Rejection under 35 U.S.C. § 103(a) over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202).....	24
E.	Rejection under 35 U.S.C. § 103(a) over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 35 and in further view of Daecher et al. (US Patent No. 5,840,388).....	25

F.	Rejection under 35 U.S.C. § 103(a) over Karger et al. (US Patent No. 5,840,388) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Van Alstine et al. (US Patent No. 4,690,749) and Regnier et al. (US Patent No. 5,958,202).....	26
VIII.	CLAIMS APPENDIX	37
IX.	EVIDENCE APPENDIX	43
X.	RELATED PROCEEDINGS APPENDIX.....	44

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is the assignee, GYROS PATENT AB.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

Claims 1-33 were originally filed on February 26, 2002 in this case, which is the National Phase Application of PCT Application No. EP00/12478 filed December 11, 2000 claiming priority to Swedish patent application 9904802-7, filed on December 23, 1999.

B. Current Status of Claims

Prior to examination, claims 1-33 were amended and new claims 34-41 were added in a preliminary amendment dated February 26, 2002.

Following an Office Action mailed September 23, 2004 rejecting claims 1-41, a response was filed on February 02, 2005 canceling claim 37, amending claims 1, 2, 7, 11, 13, 22, 30, 31, 33, 35, 38, and 39; and adding claims 42 – 53.

A Final Office Action was mailed on March 24, 2005 rejecting the outstanding claims 1-36 and 38-53. An amendment after final was filed May 24, 2006 canceling claims 1, 6, 29, 31, 32, 37-41, 44, 46, and 48-53; amending claims 2-5, 7-11, 13, 14, 19, 20, 27-28, 30, 33, 35, 36, 42 and 47; and adding new claim 54.

After an Advisory Action on June 8, 2005 denying entry of the amendment after final, a Request for Continued Examination was filed July 01, 2005 canceling claims 1, 6, 29, 31, 32, 37-

41, 44, 46, and 48-53; amending claims 2-5, 7-11,13, 14, 19, 20, 27-28, 30, 33, 35, 36, 42 and 47; and adding new claim 54 (identical to the denied amendment after final).

An Office Action mailed September 21, 2005, rejected the outstanding claims 2-5, 7-28, 30, 34-36, 42, 43, 45, 47 and 54. A response was filed on March 21, 2006 canceling claims 9, 33, 36 and 47; and amending claims 7 and 30.

A Final Office Action was mailed on June 6, 2006 rejecting the outstanding claims 2-5, 7, 8, 10-28, 30, 34, 35, 42, 43, 45, and 54.

Applicant filed a Notice of Appeal on September 06, 2006.

Subsequent to the Notice of Appeal, Applicant filed an Amendment After Final on October 30, 2006 and a Supplemental Amendment After final on October 31, 2006, pursuant to 35 CFR § 41.33(a) and 35 CFR § 1.116(b)(2), to address the outstanding claim objections in the pending Final Office Action of June 6, 2006.

C. Claims On Appeal

The claims on appeal are claims 2-5, 7, 8, 10-28, 30, 34, 35, 42, 43, 45, and 54.

IV. STATUS OF AMENDMENTS

Applicant filed a response with amendments on March 21, 2006. The Examiner's final Office Action mailed June 6, 2006 acknowledged entry of these amendments. An Amendment After Final filed on October 30, 2006 and a Supplemental Amendment After Final filed on October 31, 2006 were entered into the record November 7, 2006. There are no amendments to the claims outstanding.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Paragraph numbers refer to the published application 20020125135. The claimed subject is exemplified in independent claim 7. Independent claim 7 comprises a microfluidic device

being in a dry state that is capable of being rehydrated, said device comprises a set of one or more covered microchannel structures manufactured in the surface of a planar substrate, wherein each microchannel structures comprises: a) more than one functional part wherein at least one of said functional parts is selected from the group consisting of a volume defining unit, a mixing cavity, and a waste cavity; paragraph [0057] b) wherein reduced non-specific adsorption and hydrophilicity have been optimized by a coating exposing a non-ionic hydrophilic polymer on the surface of at least one of said at least one functional parts such that an aqueous liquid is capable of entering the functional part by self-suction when the liquid has passed the entrance of the functional part paragraphs [0024]; [0026] and [0062]; and c) wherein the device is adapted for mass transport of solutes and/or particles between different functional parts of each microchannel structure by a liquid flow caused by non-electrokinetic forces paragraphs [0022]; [0058].

VI. GROUNDS OF OBJECTION TO BE REVIEWED ON APPEAL

- A. Whether claims 2-5, 7, 8, 10-13, 18-23, 28, 34, 35, 42, 43, 45, and 54 were properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202).**
- B. Whether claims 14 and 24-26 were properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claims 7 and 20 and in further view of Bergstrom et al. (US Pat No. 5,250,613).**
- C. Whether claims 15-17 were properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 11 and in further view of Malmsten et al., Effect of Chain Density on Inhibition of Protein Adsorption by Poly(ethylene glycol) Based Coatings, *Journal Of Colloid And Interface Science* 1998, vol. 202; no. 2, pages 507-517.**

- D. Whether claim 30 was properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202).
- E. Whether claim 45 was properly rejected under 35 U.S.C. § 103(a) as unpatentable over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 35 and in further view of Daecher et al. (US Patent No. 5,840,388).
- F. Whether claims 7 and 27 were properly rejected under 35 U.S.C. § 103(a) as unpatentable over Karger et al. (US Patent No. 5,840,388) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Van Alstine et al. (US Patent No. 4,690,749) and Regnier et al. (US Patent No. 5,958,202).

VII. ARGUMENT

- A. Rejection under 35 U.S.C. § 103(a) over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202)

1. Claims 7, 2, 3, 4, 5, 8, 10, 11, 18, 19, 20, 21, 22, 23, 28, 34, 35, and 54

a. Legal Background

Office policy is to follow *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), in the consideration and determination of obviousness under 35 U.S.C. 103(a). As quoted above, the four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

MPEP § 2141

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an

independent claim is nonobvious under 35 U.S.C. 103(a), then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

MPEP § 2143.03.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

MPEP § 2143.01.

b. **Graham Factors: Level of Skill in the Art**

For the pending rejections under 35 U.S.C. § 103(a), the Examiner is required to apply the obviousness analysis mandated by the US Supreme Court ("*Graham* Factors"). MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). One element of the *Graham* Factors is resolving the level of ordinary skill in the pertinent art. *Id.* This is a pivotal aspect of the obviousness inquiry because one must assess the obviousness of a claim from the perspective of one of ordinary skill in the art. *Dystar Textilfarben GmbH* 2006 U.S. App. LEXIS 24642 at *13-*17 ("Because the parties disagree over the relevance of the cited prior art, which, fundamentally, is a disagreement over the level of ordinary skill in the art, we address this third *Graham* factor first.").

The file history discusses in several places what one of skill in the art would do with cited art. However, the file history does not mention the *Graham* Factors until the most recent Office Action. 06/06/06, pg. 3. While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. Applicant respectfully requests the Board still consider Applicant's further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

c. **Graham Factors: Scope and Contents of the Prior Art**

i. **Amigo**

The pending rejection relies on Amigo (US Patent No. 5,935,401) as the primary reference. The file's characterization of the contents of Amigo is erroneous.

Volume Defining Unit

The pending rejection's position is that a "volume defining unit" is any microstructure cavity because any cavity will "define" the volume within it. Based on this interpretation, Amigo is alleged to meet this limitation by virtue of having microchannels in some embodiments. During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Even under this generous standard of review, the rejection's interpretation is unsound. A "volume defining unit" is grammatically distinguished from structures generally by virtue of being listed among other types of structures. To one of ordinary skill in the art in microfluidic devices, a "volume defining unit" is structured to permit a specific amount of fluid to progress through the unit to subsequent microstructures (i.e. fluid metering). *See, e.g.*, US Pat. No. 6,919,058 (IDS cited reference AW) and references cited therein. Functional limitations are permissible. MPEP § 2173.05(g). The rejection disregards this limitation as a convenient, but impermissible way to avoid one of the many insufficiencies of the pending obviousness rejection. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

Non-electrokinetic Fluid Transport

The rejection asserts that a working example in Amigo is a microfluidic device with "a set of one or more covered microchannel structures...adapted for mass transport of solutes and/or particles between different function[al] parts of each microchannel structure by a liquid flow caused by non-electrokinetic forces." Office Action 06/06/06, pg. 9, 1st full paragraph; Amigo Col. 9, ln. 45-48. The cited passage describes a step in the process of modifying a polymeric surface and discloses a variety of means for removing excess "first monomer." There is no teaching in Amigo that microchannel structures are to be coated by polymers after a cover is attached. Col. 7, ln. 49 – Col. 8, ln. 13. There is basis on record that any devices of Amigo

are adapted for flow *between* functional parts. Functional limitations are permissible. MPEP § 2173.05(g). Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

As a supplemental matter, the rejection cites the pending application's disclosure of electroosmotic flow as one means for bulk fluid movement. Published application 2002/0125135 at [0058]. The rejection appears to be bolstering its positions on obviousness by resort to Applicant's own disclosure. This goes to the heart of the obviousness inquiry and is, of course, not allowed. MPEP § 2145(X.A.); *In re McLaughlin* 443 F.2d 1392, 1395.

ii. Zimmer et al.

Capillaries

The pending rejection cites Zimmer et al. as disclosing "the ability of capillaries with sufficiently hydrophilic surfaces, including polymer surfaces, to draw in aqueous material upon contact." Zimmer discloses "capillary channels" able to draw in, e.g., blood samples. *See* claim 1. These channels are not capillaries because they have widths of several millimeters. Col. 3, ln. 3-6 (US Patent No. 7,008,799 English translation); *Compare* capillary electrophoresis discussion in US Patent No. 6,322,682 (IDS ref. H). Thus, the rejection attempts to supply an element from Zimmer et al. that the reference does not contain. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

iii. Karger et al.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); MPEP § 2112.

The pending rejection relies on allegedly inherent disclosure in the Karger et al. reference to supply the limitation: "being in a dry state that is capable of being rehydrated...." Office Action 06/06/06, pg. 7, last paragraph. There is no extrinsic evidence cited or reasoning

advanced to support the position that Karger et al. inherently meets this limitation. Because the rejection is facially insufficient, this rejection should, at a minimum, be vacated and remanded for further examination.

iv. Regnier et al.

The pending rejection cites Regnier et al. as disclosing 1) bulk fluid motion caused by non-electrokinetic means and 2) using a non-electrokinetic means of moving fluid within the channels. Office Action 06/06/06, pg. 8, last 2 paragraphs. The cited passage in Regnier et al. discloses standard methods of sample injection into capillary electrophoresis systems. Col. 37, ln. 54-58. Regnier et al is applied to supply the limitation:

“the device is adapted for mass transport of solutes and/or particles between different function parts of each microchannel structure by a liquid flow caused by non-electrokinetic forces.”

It is not clear from the pending rejection, but the pending rejection appears to assert that Regnier et al. discloses non-electrokinetic means of moving fluid “between different function[al] parts.” The cited passage describing sample injection into an electrophoretic device is not a disclosure of any movement between different functional parts. Office action 06/06/06, pg. 9, 1st full paragraph. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

v. Amigo plus Karger et al.

The pending rejection argues that in a device disclosed by Amigo as modified Karger et al. (i.e. having a dried and rehydratable polymeric coating) “entry of liquid by ‘self-suction’ would inherently result....” Office Action 06/06/06, pg. 7, last paragraph. Setting aside the propriety of the combination, there is no extrinsic evidence cited or reasoning advanced to support the position that the devices in Amigo modified according to Karger et al., inherently meets this limitation. On the contrary, the examples in Karger et al. teach sample injection, not capillary introduction. Col. 7, ln. 40-Col. 8, ln. 44. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

d. Graham Factors: Ascertaining the differences between the prior art and the claims in issue

Non-Specific Adsorption And Hydrophilicity

Amigo discusses polymer coatings in electrophoretic channels for the purpose of 1) enhancement, reduction or selectivity in entity adsorption to the surface of the chamber and 2) enhancing or reducing the occurrence of electroosmotic flow (EOF) in electrophoretic chambers. Col. 4, ln. 65 to Col. 5, ln. 3.; Col. 5, ln. 29-33. Amigo discusses the use of hydrophilic polymers to achieve control of EOF and non-specific adsorption. Col. 5, ln. 3.- Col. 5, ln. 48. The pending rejection equates this disclosure with limitation b) of claim 7. The rejection then goes on to cite *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) for the proposition that optimizing know result affecting variables through routine experimentation is not inventive. A particular parameter must first be recognized as a result-effective variable before the determination of the optimum or workable ranges of a variable might be characterized as routine experimentation. MPEP § 2144.05. The result claim 7 is directed to optimizing is the balancing of “reduced non-specific adsorption and hydrophilicity” and the functional property: “an aqueous liquid is capable of entering the functional part by self-suction when the liquid has passed the entrance of the functional part.” *See also* Published application at [0011] – [0015]. Optimizing hydrophilicity to balance reduced non-specific adsorption and the capacity for capillary movement of a fluid is not disclosed nor hinted at by Amigo. There is no basis on record for concluding the art recognized that the two parameters of capillary suction and non-specific adsorption need balancing. The rejection’s premise regarding the disclosure in Amigo is thus off point, analogous to the situation discussed by *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). MPEP § 2144.05.

e. Teaching, Suggestion, or Motivation to Combine or Modify the Art

The Federal Circuit Court of Appeals has recently expounded upon the motivation to combine requirement. *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). In essence, the Federal Circuit jurisprudence enforces the *Graham* mandate by requiring one to explain *why* something would have been obvious to one of ordinary skill in the art. *E.g., Id.* at n3. To this end, the Federal Circuit has consistently required a detailed accounting of the reasoning and factual basis for an allegation that one of ordinary

skill in the art would have derived the claimed subject matter. *In re Lee*, 277 F.3d 1338, 1341, 1344-45 (Fed. Cir. 2002). In particular, when relying on common knowledge within the art, a rejection must spell out with clarity and detail why one of skill in the art would be expected to have such knowledge. *Id.* Conclusory statements, unsupported by any meaningful explanation, do not meet the *Graham* mandate's requirements, as explained by the Federal Circuit. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

i. Modifying Amigo by Reference to Zimmer et al.

The pending rejection summarily answers the question why the claimed subject matter in pending claim 7 is obvious as follows:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Amigo by specifically providing a hydrophilic surface (such as a hydrophilic polymer surface) at a channel opening to draw aqueous fluids in by capillarity, as taught by Zimmer et al, because it would facilitate sample introduction in some applications. (e.g. biosensor)

Office Action 06/06/06, pg. 7, 3rd paragraph.

The rejection advances the idea that modifying Amigo by reference to Zimmer et al. would render the claimed subject matter obvious because the modification would commend itself to one of skill in the art for "some applications." Without the explicit example of biosensors, this stated motivation is facially insufficient under *In re Lee* because it is conclusory and unsubstantiated. 277 F.3d at 1344-45. Even taking into account the cited example application, the rejection is insufficient. There is no basis on record for ascribing biosensor applications to the Amigo disclosure. The word biosensor does not appear in Zimmer et al. Biosensor only appears in Amigo in the title of a book, cited as a reference for polymer material surface modification techniques. The rejection gives no explanation for what is meant by a biosensor or what is the knowledge in the art that would lead one to modify Amigo based on Zimmer et al. to derive a biosensor. Because the rejection is grounded on an unsubstantiated and unexplained

motivation to combine, the rejection of claim 7 should be reversed under governing Federal Circuit precedent. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

Alternatively, the rejection is arbitrary and capricious and/or lacks substantial evidence of record and thus fails to satisfy the standards set forth in the Administrative Procedures Act (APA). 5 U.S.C. § 706(2)(A) & (E); *Dickinson v. Zurko*, 527 U.S. 150 (1999); *Mazzari v. Rogan*, 323 F.3d 1000, 1004-1005 (Fed. Cir. 2003); *Association of Data Processing Service Organizations, Inc. v. Board of Governors of Federal Reserve System*, 745 F.2d 677, 683-684 (“When the arbitrary or capricious standard is performing that function of assuring factual support, there is no substantive difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a ‘nonarbitrary’ factual judgment supported only by evidence that is not substantial in the APA sense -- i.e., not ‘enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn . . . is one of fact for the jury,’” (citations omitted));

“Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consolidated Edison Co. v. NLRB*, 305 U.S. 197 (1938). Applied to the case at hand, the rejection (erroneously) identifies elements in various references that allegedly could be combined to meet some set of limitations in claim 7. This is, in and of itself, not evidence that such a combination is obvious. *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). The pending rejection thus represents the extreme case of no evidence to support the conclusion that the claimed subject matter is obvious. Because the rejection against claim 7 constitutes an arbitrary and capricious decision and is lacking substantial evidence in support, the rejection should be reversed as violating the APA. 5 U.S.C. § 706(2)(A) & (E).

- ii. Modifying Amigo by Reference to Karger et al.

The pending rejection summarily answers the question why the claimed subject matter in pending claim 7 is obvious as follows:

Office Action 06/06/06, pg. 8, 1st paragraph.

Addressing claim 7, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Amigo by providing the device in a dry state that is capable of being rehydrated, as taught by Karger et al, because it would facilitate device storage and shipping. The convenience of being able to store devices for later use, as compared to preparing the coatings immediately prior to use would have been obvious and highly desirable to one having ordinary skill in the art.

The rejection advances the idea that modifying Amigo by reference to Karger et al. would render the claimed subject matter obvious because the modification would commend itself to one of skill in the art. The rejection comes to the conclusion that storage and shipping would be facilitated and it would make ultimate device use more convenient than de novo preparation immediately prior to use. This stated motivation is insufficient under *In re Lee* because it is conclusory and unsubstantiated. 277 F.3d at 1344-45. There is no basis on record for why or how a modified device described by Amigo would be easier to store or ship (in comparison to what?). The rejection gives no explanation for what knowledge in the art would lead one to modify Amigo based on Karger et al. Because the rejection is grounded on an unsubstantiated and unexplained motivation to combine, the rejection of claim 7 should be reversed under governing Federal Circuit precedent. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

Alternatively, the rejection is arbitrary and capricious and/or lacks substantial evidence of record and thus fails to satisfy the standards set forth in the Administrative Procedures Act (APA). 5 U.S.C. § 706(2)(A) & (E); *Dickinson v. Zurko*, 527 U.S. 150 (1999); *Mazzari v. Rogan*, 323 F.3d 1000, 1004-1005 (Fed. Cir. 2003); *Association of Data Processing Service Organizations, Inc. v. Board of Governors of Federal Reserve System*, 745 F.2d 677, 683-684 (“When the arbitrary or capricious standard is performing that function of assuring factual

support, there is no substantive difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a ‘nonarbitrary’ factual judgment supported only by evidence that is not substantial in the APA sense -- i.e., not ‘enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn . . . is one of fact for the jury,’” (citations omitted));

“Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consolidated Edison Co. v. NLRB*, 305 U.S. 197 (1938). Applied to the case at hand, the rejection identifies (purported inherent) elements in various references that allegedly could be combined to meet some set of limitations in claim 7. This is, in and of itself, not evidence that such a combination is obvious. *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). The pending rejection thus represents the extreme case of no evidence to support the conclusion that the claimed subject matter is obvious. Because the rejection against claim 7 constitutes an arbitrary and capricious decision and is lacking substantial evidence in support, the rejection should be reversed as violating the APA. 5 U.S.C. § 706(2)(A) & (E).

iii. Modifying Amigo by Reference to Regnier et al.

The pending rejection summarily answers the question why the claimed subject matter in pending claim 7 is obvious as follows:

It would also have been obvious to one having ordinary skill in the art to further modify the device of Amigo by using a non-electrokinetic means of moving fluid within the channels, as taught by Regnier et al, because it would prevent electrophoretic bias in the injection procedure. Additionally, if the object of the application of the hydrophilic coating was to minimize or substantially eliminate electroosmotic flow (See Amigo, Office Action 00/00/00, pg. 8-9, bridging paragraph, Column 5, lines 9-16), then a non-electrokinetic means of bulk fluid motion would be required in order to have efficient fluid flow.

Electrophoretic Bias

However, the argument regarding electrophoretic bias is not supported or explained. This stated motivation is insufficient under *In re Lee* because it is conclusory and unsubstantiated. 277 F.3d at 1344-45. There is no basis on record for why or how a modified device described by Amigo would improve or avoid “electrophoretic bias.” The concept of “electrophoretic bias” is not discussed in Amigo or Regnier et al. (or on the record). Amigo discloses electroosmotic flow (EOF) may change the electrophoretic movement profile of entities through the electrophoretic medium. Col. 1, ln. 18-24. Even assuming this is the electrophoretic bias to which the rejection refers, there is no support for the position that EOF has any impact on sample introduction (in contrast to electrophoretic resolution.). Because the rejection is grounded on an unsubstantiated and unexplained motivation to combine, the rejection of claim 7 should be reversed under governing Federal Circuit precedent. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

Alternatively, the rejection is arbitrary and capricious and/or lacks substantial evidence of record and thus fails to satisfy the standards set forth in the Administrative Procedures Act (APA). 5 U.S.C. § 706(2)(A) & (E); *Dickinson v. Zurko*, 527 U.S. 150 (1999); *Mazzari v. Rogan*, 323 F.3d 1000, 1004-1005 (Fed. Cir. 2003); *Association of Data Processing Service Organizations, Inc. v. Board of Governors of Federal Reserve System*, 745 F.2d 677, 683-684 (“When the arbitrary or capricious standard is performing that function of assuring factual support, there is no substantive difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a ‘nonarbitrary’ factual judgment supported only by evidence that is not substantial in the APA sense -- i.e., not ‘enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn . . . is one of fact for the jury,’” (citations omitted));

“Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consolidated Edison Co. v. NLRB*, 305 U.S. 197 (1938). Applied to the case at hand, the rejection purports to identify elements in various references that allegedly could be combined to meet some set of limitations in claim 7. This is, in and of itself, not evidence that such a combination is obvious. *In re Mills*,

916 F.2d 680, 682 (Fed. Cir. 1990). The pending rejection thus represents the extreme case of no evidence to support the conclusion that the claimed subject matter is obvious. Because the rejection against claim 7 constitutes an arbitrary and capricious decision and is lacking substantial evidence in support, the rejection should be reversed as violating the APA. 5 U.S.C. § 706(2)(A) & (E).

Non-electrokinetic Flow

The rejection attempts to reason out why non-electrokinetic flow would be the natural and required result of modifying Amigo by Regnier et al. The reasoning is that Amigo discloses the elimination of EOF. Without EOF, some other means of bulk fluid flow would have to be substituted to have “efficient” bulk fluid flow. Allegedly, the choice of one of ordinary skill in the art would be the non-electrokinetic means covered by the pending claims. A key aspect in this line of reasoning is the pre-supposed need for some type of bulk fluid flow in the devices of Amigo. Electrophoresis is the movement of entities *through* a medium as a result of an applied electric field. Amigo Col. 1, ln. 7-12. Bulk fluid flow, efficient or otherwise, is not thus generally part of electrophoretic processes (in contrast with many chromatographic techniques). The efficient bulk flow argument is thus grounded in factual error and should be reversed.

2. Claim 42

a. Graham Factors: Level of Skill in the Art

While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). Applicant respectfully requests the Board still consider Applicant’s further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

b. Graham Factors: Scope and Contents of the Prior Art

The pending rejection cites Amigo as disclosing a “surface carrying the coat is made of inorganic material,” citing glass as an example. Office Action 06/06/06, pg. 6, 4th paragraph. Amigo discloses:

Although only the material in the region of surface modification will necessarily be the rigid, solid polymeric base material, the entire chamber, e.g. capillary or planar substrate having a microchannel on its surface, may be fabricated from the base polymeric material. Alternatively, the chamber may be fabricated from two or a plurality of different materials, so one has a chamber fabricated from a composite material. For example, in the walls of the chamber the base polymeric material can be present over a layer of another material, where the different material may serve to modify the physical properties of the substrate. Where desired, the second material present in the composite substrate may be a heat dissipating material which serves to absorb heat produced in the electrophoretic medium during electrophoresis. Materials that provide for heat absorption and dissipation and may be present in a composite substrate include glasses, ceramics, metals and the like.

Col. 3, ln. 8-19 (emphasis added).

Amigo not taken out of context, clearly discloses only the polymeric base material is coated and not the heat dissipating glass structures. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

3. Claim 43

a. Graham Factors: Level of Skill in the Art

While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App.

LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). Applicant respectfully requests the Board still consider Applicant's further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

b. **Graham Factors: Scope and Contents of the Prior Art**

Claim 43 adds the limitation "the polymer skeleton is an inorganic polymer." This is read in context of claim 20 which claims a "non-ionic hydrophilic polymer is attached to a polymer skeleton that is attached to the part surface." The rejection cites Amigo Col. 3, ln. 47-49: "Polymers finding use will be synthetic, usually organic and may be addition or condensation polymers." Taken out of context, this sentence would seem to support the rejection. Reading Amigo it becomes clear that the rejection is specious. The sentence refers to the base material for the electrophoretic structure and not the polymeric coating engrafted thereon. *Id.* at Col. 3, ln. 36-47; *Compare* Col. 4, ln. 10-18. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

B. Rejection under 35 U.S.C. § 103(a) over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claims 7 and 20 and in further view of Bergstrom et al. (US Pat No. 5,250,613).

1. **Claims 14, 24-26**

These claims are rejected on a further modification of the device derived by combining Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 7 & 20. Because the rejections against claim 7 & 20 are in error, the further rejection of claims 14, 24-26 should also be reversed.

a. **Graham Factors: Level of Skill in the Art**

While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of

law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). Applicant respectfully requests the Board still consider Applicant's further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

b. Graham Factors: Scope and Contents of the Prior Art

The rejections of claims 14, 24-26 are unsupported on grounds separate from those of claim 7 & 20. Each claims' limitation regarding the polymeric coating is rejected:

because Bergstrom et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis. Selection of a known separation medium in capillary electrophoresis falls well within the level of ordinary skill in the art.

Office Action 06/06/06, pg. 10, bridging paragraph – pg. 11, 1st full paragraph.

The rejection is thus premised on Bergstrom et al. disclosing an alternative electrophoretic separation medium suitable for the capillary electrophoresis disclosed by Amigo MPEP § 2144.06 (SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE). This premise is wrong. Bergstrom et al. relates to the following applications:

The immobilization of proteins and other biopolymers to solid surfaces is an established technique for a number of biochemical applications, such as solid phase diagnostics, analysis with biosensors, affinity chromatography, extracorporeal therapy, and bio-organic synthesis. In all of these cases, the biopolymer is bonded to a solid surface, and its biological activity then utilized for a specific purpose, such as in solid phase diagnostics, extracorporeal therapy, biological synthesis, and treatment of implants.

[N]onspecific adsorption by electrostatic attraction and hydrophobic interaction is an undesired phenomenon for the above-mentioned applications.

One way of drastically reducing the adsorption proteins and other biopolymers on solid surfaces is to provide the surfaces with a layer of an uncharged hydrophilic polymer.

According to the invention, it has now proved possible to improve the immobilization of desirable polymers, while simultaneously obtaining a thoroughly developed hydrophilic surface of low spontaneous adsorption.

Col. 1, ln. 8-17; ln.; Col. 2, ln. 5-7, ln. 13-16; Col. 3, ln. 10-14.

Nothing in Bergstrom et al. teaches or suggests anything related to capillary electrophoresis or suitable separation media for use therein. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

C. Rejection under 35 U.S.C. § 103(a) over over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 11 and in further view of Malmsten et al., Effect of Chain Density on Inhibition of Protein Adsorption by Poly(ethylene glycol) Based Coatings, *Journal Of Colloid And Interface Science* 1998, vol. 202; no. 2, pages 507-517.

1. Claims 15, 16 and 17

a. Graham Factors: Level of Skill in the Art

While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). Applicant respectfully requests the Board still consider Applicant's further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

b. Graham Factors: Scope and Contents of the Prior Art

These claims are rejected on a further modification of the device derived by combining Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 11. Because the rejections against claim 11 are in error, the further rejection of claims 15-17 should also be reversed.

The rejection is also premised on Malmsten et al. disclosing an alternative electrophoretic separation medium suitable for the capillary electrophoresis disclosed by Amigo Office Action 06/06/06, pg. 10, bridging paragraph – pg. 11, 1st full paragraph.; MPEP § 2144.06 (SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE). As with Bergstrom et al., nothing in Malmsten et al. teaches or suggests anything related to capillary electrophoresis or suitable separation media for use therein. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

D. Rejection under 35 U.S.C. § 103(a) over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202).

1. Claim 30

a. Graham Factors: Level of Skill in the Art

While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). Applicant respectfully requests the Board still consider Applicant's further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

b. Graham Factors: Scope and Contents of the Prior Art

Claim 30 is rejected as an expressly suggested application of the device derived from combining the above cited references, as discussed for claim 7 in the pending rejection. Office Action 06/06/06, pg. 12-13. Any process steps are alleged to be inherent to the suggested applications. *Id.* at pg 14. While this rejection is listed separately from the claim 7 rejection, it expressly relies upon the rejection of claim 7. Because the rejection of claim 7 is incorrect, as discussed above, the rejection of the related method claim 30 is also in error and should be reversed.

- E. Rejection under 35 U.S.C. § 103(a) over Amigo (US Patent No. 5,935,401) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Karger et al. (US Patent No. 5,840,388) and Regnier et al. (US Patent No. 5,958,202) as applied to claim 35 and in further view of Daecher et al. (US Patent No. 5,840,388).**

1. Claim 45

a. Graham Factors: Level of Skill in the Art

While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). Applicant respectfully requests the Board still consider Applicant's further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

b. Graham Factors: Scope and Contents of the Prior Art

While this rejection is listed separately from the claim 7 rejection, it expressly relies upon the rejection of claim 35, which ultimately refers back to claim 7. Because the rejection of claim 7 is incorrect, as discussed above, the rejection of the claim 45 is also in error and should be reversed.

The rejection further cites Daecher et al. as disclosing use of norbornene based plastics as suitable for use in manufacturing microfluidic devices. Office Action 06/06/06, pg. 14, 1st paragraph. The rejection thus concludes it would be obvious to substitute norborene for the plastics disclosed in Amigo because Daecher et al. proves the art recognized equivalency of norborene for this purpose. *Id.* at 2nd paragraph; MPEP § 2144.06. Daecher does disclose adaptation of the disclosed invention to the manufacture of microfluidic devices. Col. 9, ln. 55-65. Several polymeric substances are identified as suitable for this particular application. Col. 9, ln. 61-65. Norborene is not so identified. *Id.* Elsewhere, the disclosure provides a long list of plastics including norbornene. Col. 14, ln. 9-32. These plastics are listed as “thermoplastic resins for which the process of the present invention is useful....” *Id.* at ln. 9-11. The process of the present invention is described at Col. 3, ln. 18-28 and relates to the manufacture of an “optical storage medium.” *See also* claims 1-16. Optical storage media are compact disks (CDs), digital versatile disks (DVDs), etc. Col. 5, ln. 13-17. A reference teaching norborene’s suitability for manufacturing CD’s does not teach suitability for use in manufacturing microfluidic devices by virtue of being in the same disclosure. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

F. Rejection under 35 U.S.C. § 103(a) over Karger et al. (US Patent No. 5,840,388) in view of Zimmer et al. (DE 197 53 847; English version US Patent No. 7,008,799), Van Alstine et al. (US Patent No. 4,690,749) and Regnier et al. (US Patent No. 5,958,202).

1. Claim 7

a. Graham Factors: Level of Skill in the Art

While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App.

LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). Applicant respectfully requests the Board still consider Applicant's further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

b. Graham Factors: Scope and Contents of the Prior Art

i. Karger et al.

The pending rejection relies on Karger et al. (US Patent No. 5,840,388) as the primary reference. The file's characterization of the contents of Karger et al. is erroneous.

Covered microstructures in the surface of a planar structure

The rejection states that Karger et al. discloses covered microstructures in the surface of a planar structure. Office Action 06/06/06, pg. 14, 4th paragraph. The rejection cites the claims drawn to a "microcapillary column" and the definition:

The terms "CE column" or "microcapillary column" are meant to include a vessel of any shape in which capillary electrophoresis can be carried out. **For example, it is also known to use chips with open grooves microfabricated into the surface of the chip for capillary electrophoresis.**

Col. 2, ln. 27-32 (emphasis added).

Chips with open grooves do not equal planar substrates with covered microchannel structures. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

Drying and Rehydrating

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); MPEP § 2112.

The pending rejection relies on allegedly inherent disclosure in the Karger et al. reference to supply the limitation: "being in a dry state that is capable of being rehydrated...." Office

Action 06/06/06, pg. 14, last paragraph. In addition, the rejection further attributes the inherent property of capillary suction of liquids to the devices disclosed by Karger et al. Office Action 06/06/06, pg 17, 1st paragraph. There is no extrinsic evidence cited or reasoning advanced to support the position that Karger et al. inherently meets either limitation. Because the rejection is facially insufficient, this rejection should, at a minimum, be vacated and remanded for further examination.

ii. Regnier et al.

Volume Defining Unit

The pending rejection's implicit position is that a "volume defining unit" is any microstructure cavity because any cavity will "define" the volume within it. (See above claim 7 discussion regarding Amigo and Volume Defining Units). Based on this interpretation, Regnier et al. is alleged to meet this limitation by virtue of having microchannels. During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Even under this generous standard of review, the rejection's interpretation is unsound. A "volume defining unit" is grammatically distinguished from structures generally by virtue of being listed among other types of structures. To one of ordinary skill in the art in microfluidic devices, a "volume defining unit" is structured to permit a specific amount of fluid to progress through the unit to subsequent microstructures (i.e. fluid metering). *See, e.g.*, US Pat. No. 6,919,058 (IDS cited reference AW) and references cited therein. Functional limitations are permissible. MPEP § 2173.05(g). The rejection disregards this limitation as a convenient, but impermissible way to avoid one of the many insufficiencies of the pending obviousness rejection. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

iii. Zimmer et al.

Capillaries

The pending rejection cites Zimmer et al. as disclosing "the ability of capillaries with sufficiently hydrophilic surfaces, including polymer surfaces, to draw in aqueous material upon

contact.” Zimmer discloses “capillary channels” able to draw in, e.g., blood samples. *See* claim 1. These channels are not capillaries because they have widths of several millimeters. *See* Col. 3, ln. 3-6 (US Patent No. 7,008,799 English translation); *Compare* capillary electrophoresis discussion in US Patent No. 6,322,682 (IDS ref. H). Thus, the rejection attempts to supply an element from Zimmer et al. that the reference does not contain. Because all limitations must be accounted for in making a rejection under 35 U.S.C. § 103(a), the pending rejection should be reversed. MPEP § 2143.03.

c. Teaching, Suggestion, or Motivation to Combine or Modify the Art

The Federal Circuit Court of Appeals has recently expounded upon the motivation to combine requirement. *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). In essence, the Federal Circuit jurisprudence enforces the *Graham* mandate by requiring one to explain *why* something would have been obvious to one of ordinary skill in the art. *E.g., Id.* at n3. To this end, the Federal Circuit has consistently required a detailed accounting of the reasoning and factual basis for an allegation that one of ordinary skill in the art would have derived the claimed subject matter. *In re Lee*, 277 F.3d 1338, 1341, 1344-45 (Fed. Cir. 2002). In particular, when relying on common knowledge within the art, a rejection must spell out with clarity and detail why one of skill in the art would be expected to have such knowledge. *Id.* Conclusory statements, unsupported by any meaningful explanation, do not meet the *Graham* mandate’s requirements, as explained by the Federal Circuit. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

i. Modifying Karger et al by Reference to Regnier et al.

Electrophoretic Bias

The argument regarding electrophoretic bias is not supported or explained. Office Action 06/06/06, pg. 16, 3rd paragraph (compare to analogous claim 7 rejection). This stated motivation is insufficient under *In re Lee* because it is conclusory and unsubstantiated. 277 F.3d at 1344-45. There is no basis on record for why or how a modified device derived from Karger et al plus Regnier et al. would improve or avoid “electrophoretic bias.” The concept of “electrophoretic

bias” is not discussed in Karger et al. or Regnier et al. (or on the record). Amigo discloses electroosmotic flow (EOF) may change the electrophoretic movement profile of entities through the electrophoretic medium. Col. 1, ln. 18-24. This phenomena is taken advantage of by Karger et al. for a “dynamic cation exchanger” embodiment. Col. 6, ln. 46-53. Even assuming these relate to the electrophoretic bias to which the rejection refers, there is no support for the position that EOF has any impact on sample introduction (in contrast to electrophoretic resolution.). Because the rejection is grounded on an unsubstantiated and unexplained motivation to combine, the rejection of claim 7 should be reversed under governing Federal Circuit precedent. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

Alternatively, the rejection is arbitrary and capricious and/or lacks substantial evidence of record and thus fails to satisfy the standards set forth in the Administrative Procedures Act (APA). 5 U.S.C. § 706(2)(A) & (E); *Dickinson v. Zurko*, 527 U.S. 150 (1999); *Mazzari v. Rogan*, 323 F.3d 1000, 1004-1005 (Fed. Cir. 2003); *Association of Data Processing Service Organizations, Inc. v. Board of Governors of Federal Reserve System*, 745 F.2d 677, 683-684 (“When the arbitrary or capricious standard is performing that function of assuring factual support, there is no substantive difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a ‘nonarbitrary’ factual judgment supported only by evidence that is not substantial in the APA sense -- i.e., not ‘enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn . . . is one of fact for the jury,’” (citations omitted));

“Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consolidated Edison Co. v. NLRB*, 305 U.S. 197 (1938). Applied to the case at hand, the rejection purports to identify elements in various references that allegedly could be combined to meet some set of limitations in claim 7. This is, in and of itself, not evidence that such a combination is obvious. *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). The pending rejection thus represents the extreme case of no evidence to support the conclusion that the claimed subject matter is obvious. Because the rejection against claim 7 constitutes an arbitrary and capricious decision and is lacking

substantial evidence in support, the rejection should be reversed as violating the APA. 5 U.S.C. § 706(2)(A) & (E).

ii. Modifying Karger et al. by Reference to Zimmer et al.

The rejection advances the idea that modifying Karger et al. by reference to Zimmer et al. would render the claimed subject matter obvious because the modification would commend itself to one of skill in the art for “some applications.” Office Action 06/06/06, pg. 16, last paragraph. Without the explicit example of biosensors, this stated motivation is facially insufficient under *In re Lee* because it is conclusory and unsubstantiated. 277 F.3d at 1344-45. Even taking into account the cited example application, the rejection is insufficient. There is no basis on record for ascribing biosensor applications to the Karger et al. disclosure. The word biosensor does not appear in Zimmer et al. or Karger et al. Biosensor only appears in Amigo in the title of a book, cited as a reference for polymer material surface modification techniques. The rejection gives no explanation for what is meant by a biosensor or what is the knowledge in the art that would lead one to modify Karger et al. based on Zimmer et al. to derive a biosensor. Because the rejection is grounded on an unsubstantiated and unexplained motivation to combine, the rejection of claim 7 should be reversed under governing Federal Circuit precedent. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

Alternatively, the rejection is arbitrary and capricious and/or lacks substantial evidence of record and thus fails to satisfy the standards set forth in the Administrative Procedures Act (APA). 5 U.S.C. § 706(2)(A) & (E); *Dickinson v. Zurko*, 527 U.S. 150 (1999); *Mazzari v. Rogan*, 323 F.3d 1000, 1004-1005 (Fed. Cir. 2003); *Association of Data Processing Service Organizations, Inc. v. Board of Governors of Federal Reserve System*, 745 F.2d 677, 683-684 (“When the arbitrary or capricious standard is performing that function of assuring factual support, there is no substantive difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a ‘nonarbitrary’ factual judgment supported only by evidence that is not substantial in the APA sense -- i.e., not ‘enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn . . . is one of fact for the jury,’” (citations omitted));

“Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consolidated Edison Co. v. NLRB*, 305 U.S. 197 (1938). Applied to the case at hand, the rejection (erroneously) identifies elements in various references that allegedly could be combined to meet some set of limitations in claim 7. This is, in and of itself, not evidence that such a combination is obvious. *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). The pending rejection thus represents the extreme case of no evidence to support the conclusion that the claimed subject matter is obvious. Because the rejection against claim 7 constitutes an arbitrary and capricious decision and is lacking substantial evidence in support, the rejection should be reversed as violating the APA. 5 U.S.C. § 706(2)(A) & (E).

iii. Optimization of Karger et al.

The rejection cites *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) for the proposition that optimizing known result affecting variables through routine experimentation is not inventive. Office Action 06/06/06, pg. 17, 2nd full paragraph. A particular parameter must first be recognized as a result-effective variable before the determination of the optimum or workable ranges of a variable might be characterized as routine experimentation. MPEP § 2144.05. The result claim 7 is directed to optimizing is the balancing of “reduced non-specific adsorption and hydrophilicity” and “an aqueous liquid is capable of entering the functional part by self-suction when the liquid has passed the entrance of the functional part.” See also Published application at [0011] – [0015]. Optimizing hydrophilicity to balance reduced non-specific adsorption and the capacity for capillary movement of a fluid is not disclosed nor hinted at by Karger et al., Regnier et al., or Zimmer et al. There is no basis on record for concluding the art recognized that the two parameters of capillary suction and non-specific adsorption need balancing. The rejection’s premise regarding the disclosure in Karger et al. is thus off point, analogous to the situation discussed by *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). MPEP § 2144.05.

2. **Claim 27**

a. **Graham Factors: Level of Skill in the Art**

While some of the *Graham* Factors are addressed in the file to some extent, there is no explanation of who one of ordinary skill in the art is supposed to be. Without this key element

addressed, the obviousness rejections, as they stand currently, are fatally flawed as a matter of law. At a minimum, therefore, Applicant requests the Board vacate the pending rejections and remand the application for further prosecution. MPEP § 2141; *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). Applicant respectfully requests the Board still consider Applicant's further arguments, which will establish the irreparable insufficiency of the pending rejections, regardless of the level of skill in the art.

b. Graham Factors: Scope and Contents of the Prior Art

i. Karger et al.

The pending rejection relies on Karger et al. (US Patent No. 5,840,388) as the primary reference. The file's characterization of the contents of Karger et al. is erroneous.

Covered microstructures in the surface of a planar structure

Applicant has previously addressed this deficiency under the identical heading for claim 7 under this rejection. Applicant hereby incorporates this predecessor argument as equally applicable to the rejection of claim 27.

Drying and Rehydrating

Applicant has previously addressed this deficiency under the identical heading for claim 7 under this rejection. Applicant hereby incorporates this predecessor argument as equally applicable to the rejection of claim 27.

ii. Regnier et al.

Volume Defining Unit

Applicant has previously addressed this deficiency under the identical heading for claim 7 under this rejection. Applicant hereby incorporates this predecessor argument as equally applicable to the rejection of claim 27.

iii. Zimmer et al.

Capillaries

Applicant has previously addressed this deficiency under the identical heading for claim 7 under this rejection. Applicant hereby incorporates this predecessor argument as equally applicable to the rejection of claim 27.

c. **Teaching, Suggestion, or Motivation to Combine or Modify the Art**

The Federal Circuit Court of Appeals has recently expounded upon the motivation to combine requirement. *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 2006 U.S. App. LEXIS 24642 at *10 (Fed. Cir. Oct. 3, 2006). In essence, the Federal Circuit jurisprudence enforces the *Graham* mandate by requiring one to explain *why* something would have been obvious to one of ordinary skill in the art. *E.g., Id.* at n3. To this end, the Federal Circuit has consistently required a detailed accounting of the reasoning and factual basis for an allegation that one of ordinary skill in the art would have derived the claimed subject matter. *In re Lee*, 277 F.3d 1338, 1341, 1344-45 (Fed. Cir. 2002). In particular, when relying on common knowledge within the art, a rejection must spell out with clarity and detail why one of skill in the art would be expected to have such knowledge. *Id.* Conclusory statements, unsupported by any meaningful explanation, do not meet the *Graham* mandate's requirements, as explained by the Federal Circuit. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

i. Modifying Karger et al. by Reference to Regnier et al.

Electrophoretic Bias

Applicant has previously addressed this deficiency under the identical heading for claim 7 under this rejection. Applicant hereby incorporates this predecessor argument as equally applicable to the rejection of claim 27.

ii. Modifying Karger et al by Reference to Zimmer et al.

Applicant has previously addressed this deficiency under the identical heading for claim 7 under this rejection. Applicant hereby incorporates this predecessor argument as equally applicable to the rejection of claim 27.

iii. Optimization of Karger et al.

Applicant has previously addressed this deficiency under the identical heading for claim 7 under this rejection. Applicant hereby incorporates this predecessor argument as equally applicable to the rejection of claim 27.

iv. Modifying Karger et al. by Reference to Van Alstine et al.

The rejection advances the idea that modifying Karger et al. by reference to Van Alstine et al. would render the claimed subject matter obvious because the modification “would provide a dry, less labor-intensive means of surface preparation.” Office Action 06/06/06, pg. 17, 2nd paragraph. This stated motivation is facially insufficient under *In re Lee* because it is conclusory and unsubstantiated. 277 F.3d at 1344-45. Because the rejection is grounded on an unsubstantiated and unexplained motivation to combine, the rejection of claim 27 should be reversed under governing Federal Circuit precedent. *Dystar Textilfarben GmbH*, 2006 U.S. App. LEXIS 24642 at *28-*31.

Alternatively, the rejection is arbitrary and capricious and/or lacks substantial evidence of record and thus fails to satisfy the standards set forth in the Administrative Procedures Act (APA). 5 U.S.C. § 706(2)(A) & (E); *Dickinson v. Zurko*, 527 U.S. 150 (1999); *Mazzari v. Rogan*, 323 F.3d 1000, 1004-1005 (Fed. Cir. 2003); *Association of Data Processing Service Organizations, Inc. v. Board of Governors of Federal Reserve System*, 745 F.2d 677, 683-684 (“When the arbitrary or capricious standard is performing that function of assuring factual support, there is no substantive difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a ‘nonarbitrary’ factual judgment supported only by evidence that is not substantial in the APA sense -- i.e., not ‘enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn . . . is one of fact for the jury,’” (citations omitted));

“Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consolidated Edison Co. v. NLRB*, 305 U.S. 197 (1938). Applied to the case at hand, the rejection (erroneously) identifies elements in various references that allegedly could be combined to meet some set of limitations in claim 27. This is, in and of itself, not evidence that such a combination is obvious. *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). The advanced motivation is a conclusory statement

substantively indistinguishable from “because I said so.” The pending rejection thus represents the extreme case of no evidence to support the conclusion that the claimed subject matter is obvious. Because the rejection against claim 27 constitutes an arbitrary and capricious decision and is lacking substantial evidence in support, the rejection should be reversed as violating the APA. 5 U.S.C. § 706(2)(A) & (E).

CONCLUSION

Appellants have provided arguments that overcome the pending rejections. Appellants respectfully submit that the Action’s conclusions that the claims should be rejected are unwarranted. It is therefore requested that the Board overturn the rejections of the Action. Appellants respectfully request that the Board recommend that this application proceed to allowance.

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VIII. CLAIMS APPENDIX

Claims Involved in the Appeal of Application Serial No. 10/069,827:

1. (Canceled)
2. The microfluidic device of claim 7, wherein the surface carrying the coat is made of organic material.
3. The microfluidic device of claim 7, wherein the surface of the planar substrate is made of plastics.
4. The microfluidic device of claim 7, wherein the non-ionic hydrophilic polymer is attached covalently directly to the surface or to a polymer skeleton that is attached to the surface.
5. The microfluidic device of claim 7, wherein the microfluidic device comprises more than five covered microchannel structures.
6. (Canceled)
7. A microfluidic device being in a dry state that is capable of being rehydrated, said device comprises a set of one or more covered microchannel structures manufactured in the surface of a planar substrate, wherein each microchannel structures comprises:
 - a) more than one functional part wherein at least one of said functional parts is selected from the group consisting of a volume defining unit, a mixing cavity, and a waste cavity;

b) wherein reduced non-specific adsorption and hydrophilicity have been optimized by a coating exposing a non-ionic hydrophilic polymer on the surface of at least one of said at least one functional parts such that an aqueous liquid is capable of entering the functional part by self-suction when the liquid has passed the entrance of the functional part; and

c) wherein the device is adapted for mass transport of solutes and/or particles between different functional parts of each microchannel structure by a liquid flow caused by non-electrokinetic forces.

8. The microfluidic device of claim 7, wherein each microchannel structure comprises a microcavity having a volume $\leq 1 \mu\text{l}$.

9. (Canceled)

10. The microfluidic device of claim 7, wherein the device is a round disc.

11. The microfluidic device of claim 7, wherein the non-ionic hydrophilic polymer contains hydroxy groups, ethylene oxy groups, or amide groups.

12. The microfluidic device of claim 11, wherein the non-ionic hydrophilic polymer is a polyhydroxy polymer.

13. The microfluidic device of claim 7, wherein the non-ionic hydrophilic polymer is selected from the group consisting of polysaccharides, water-soluble derivatives of polysaccharides, polyvinyl alcohols, and poly(hydroxy alkyl vinyl ether) polymers.

14. The microfluidic device of claim 7, wherein the non-ionic hydrophilic polymer is a reaction product between ethylene oxide and a dihydroxy or a polyhydroxy compound.

15. The microfluidic device of claim 11, wherein the non-ionic hydrophilic polymer comprises one or more blocks of polyoxyethylene chains.

16. The microfluidic device of claim 15, wherein the non-ionic hydrophilic polymer is polyethylene glycol.

17. The microfluidic device of claim 11, wherein the non-ionic hydrophilic polymer is polyethylene glycol which has a methoxy group at the end which does not bind to the part surface.

18. The microfluidic device of claim 11, wherein the non-ionic hydrophilic polymer comprises a plurality of amide groups.

19. The microfluidic device of claim 7, wherein the non-ionic hydrophilic polymer is a polymerisate/copolymerisate with monomers selected from the group consisting of acrylamide, methacrylamide and vinylpyrrolidone.

20. The microfluidic device of claim 7, wherein the non-ionic hydrophilic polymer is attached to a polymer skeleton that is attached to the part surface.

21. The microfluidic device of claim 20, wherein the attachment between the non-ionic hydrophilic polymer and the polymer skeleton is covalent.

22. The microfluidic device of claim 20, wherein the polymer skeleton is an organic polymer.

23. The microfluidic device of claim 20, wherein the skeleton is selected from the group consisting of cationic, anionic, and neutral polymers.

24. The microfluidic device of claim 20, wherein the skeleton is a polyamine.

25. The microfluidic device of claim 20, wherein the skeleton is a polyethylene imine.

26. The microfluidic device of claim 20, wherein the skeleton has a molecular weight 10,000-3,000,000 dalton.

27. The microfluidic device of claim 7, wherein the surface of the planar substrate without the coat is made of plastics and the part surface without coat is hydrophilized by plasma treatment or by an oxidation agent in order to introduce functional groups that allow for a subsequent attachment of the coat onto the part surface.

28. The microfluidic device of claim 7, wherein the surface of the planar substrate is made of plastics and that the plastics has a non-significant fluorescence for excitation wavelengths in the interval 200-800 nm and emission wavelengths in the interval 400-900 nm.

29. (Canceled)

30. A method of performing an analytical assay in a microchannel structure of the microfluidic device of claim 7 comprising the steps of:

- (a) preparing a sample;
- (b) transporting an analyte and reagents between different function parts of the microchannel structure by a liquid flow caused by non-electrokinetic forces and running the assay reaction within the device; and
- (c) detecting within the device the result of the assay reaction, wherein the result is a measure of an activity and/or a quantitative presence of an analyte in the sample.

Claims 31-33 are Canceled.

34. The microfluidic device of claim 3, wherein the plastics is based on a polymer of aliphatic monomers containing polymerizable carbon-carbon double bonds.

35. The microfluidic device of claim 31, wherein the monomer is selected from the group consisting of a cycloalkene, ethylene and propylene.

Claims 36-41 are Canceled.

42. The microfluidic device of claim 7, wherein the surface carrying the coat is made of inorganic material.

43. The microfluidic device of claim 20, wherein the polymer skeleton is an inorganic polymer.

44. (Canceled)

45. The microfluidic device of claim 35, wherein the cycloalkene is norbornene or substituted norbornene.

Claims 46-53 (Cancelled)

54. The microfluidic device of claim 7 further comprising functional parts of a detection cavity or a chamber for chromatography or a reaction microcavity.

IX. EVIDENCE APPENDIX

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the Patent Office is being submitted.

X. RELATED PROCEEDINGS APPENDIX

No related proceedings are referenced in II. above, hence copies of decisions in related proceedings are not provided.